UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

Lori Spellman, **Plaintiff,** **vs.** **Smith & Nephew, Inc.,** **Defendant.**	**3:16-cv-08080 JWS** **ORDER AND OPINION** **[Re: Motion at Docket 16]**

I. MOTION PRESENTED

At docket 16, defendant Smith & Nephew, Inc. ("S&N") moves pursuant to Federal Rule of Civil Procedure 12(b)(6) for an order dismissing the complaint of plaintiff Lori Spellman ("Spellman"). Spellman opposes at docket 21. S&N replies at docket 22. Oral argument was requested but would not assist the court.

II. BACKGROUND

Spellman's complaint alleges she was injured by the Birmingham Hip Resurfacing ("BHR") system, a metal-on-metal hip resurfacing prosthesis manufactured by S&N that was implanted in her hips in 2009 and 2010. In 2014 Spellman "underwent revision of her right hip due to right hip pain."[1] Her doctor informed her that the BHR system implanted in her right hip was defective and was causing her to suffer pain and "an adverse metal reaction."[2] Spellman alleges that the BHR system installed in her left hip failed as well, causing her to undergo a second revision surgery.

[1]Doc. 1 at 9 ¶ 10.

[2]*Id.* at 3-4 ¶ 11.

Spellman brings two Arizona-common-law causes-of-action against S&N: strict liability and negligence. She alleges that S&N is liable for "designing and/or manufacturing" the BHR systems in violation of the Federal Food, Drug, and Cosmetic Act" ("FDCA")[3] and related federal regulations.[4] Specifically, Spellman alleges the following ten regulatory violations:

> (1) failure to accurately establish the in vivo life expectancy of the BHR;
>
> (2) failure to validate the anticipated wear of the acetabular cup prior to its release into commercial distribution;
>
> (3) failure to establish and maintain appropriate reliability assurance testing to validate the BHR design both before and after its entry into the marketplace;
>
> (4) failure to conduct adequate bio-compatibility studies to determine the BHR's latent propensity to effuse metallic contaminants into the human blood and tissue;
>
> (5) failure to identify the component discrepancy;
>
> (6) failure to capture the component discrepancy or defect during their "Final Acceptance Activities;"
>
> (7) failure to establish and maintain procedures for implementing corrective and preventative action in response to, inter alia, complaints regarding the BHR, returned BHR, and other quality problems associated with the BHR;
>
> (8) failure to appropriately respond to adverse incident reports that strongly indicated the acetabular component was "Malfunctioning [as defined in 21 C.F.R. 803.3]," or otherwise not responding to its "Design Objection Intent;"
>
> (9) failure to complete device investigations on returned BHR and components, including the acetabular component; and
>
> (10) continuing to inject BHR into the stream of interstate commerce when it knew, or should have known, that the acetabular component was "Malfunctioning [as defined in 21 C.F.R. 803.3]" or otherwise not responding to its "Design Objective Intent."

---

[3] 21 U.S.C. § 301 *et seq*.

[4] Doc. 1 at 4 ¶ 12; 8 ¶ 21.

S&N moves for dismissal under Rule 12(b)(6), arguing that Spellman has not pleaded specific, plausible facts showing that her state law claims are not preempted by federal law.

III. STANDARD OF REVIEW

Rule 12(b)(6) tests the legal sufficiency of a plaintiff's claims. In reviewing such a motion, "[a]ll allegations of material fact in the complaint are taken as true and construed in the light most favorable to the nonmoving party."[5] To be assumed true, the allegations, "may not simply recite the elements of a cause of action, but must contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively."[6] Dismissal for failure to state a claim can be based on either "the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory."[7] "Conclusory allegations of law . . . are insufficient to defeat a motion to dismiss."[8]

To avoid dismissal, a plaintiff must plead facts sufficient to "'state a claim to relief that is plausible on its face.'"[9] "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged."[10] "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully."[11] "Where a complaint pleads facts that are 'merely

---

[5] *Vignolo v. Miller,* 120 F.3d 1075, 1077 (9th Cir. 1997).

[6] *Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011).

[7] *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990).

[8] *Lee v. City of Los Angeles*, 250 F.3d 668, 679 (9th Cir. 2001).

[9] *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

[10] *Id.*

[11] *Id.* (citing *Twombly*, 550 U.S. at 556).

consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'"[12] "In sum, for a complaint to survive a motion to dismiss, the non-conclusory 'factual content,' and reasonable inferences from that content, must be plausibly suggestive of a claim entitling the plaintiff to relief."[13]

IV. DISCUSSION

A. Federal Preemption

1. Express preemption

When Congress passed the Medical Device Amendments ("MDA")[14] to the FDCA, it "imposed a regime of detailed federal oversight" from the Food and Drug Administration ("FDA") over the introduction of new medical devices into the market.[15] The MDA contains the following clause that generally preempts states from imposing their own requirements on medical device manufacturers:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.[16]

---

[12] *Id.* (quoting *Twombly*, 550 U.S. at 557).

[13] *Moss v. U.S. Secret Serv.*, 572 F.3d 962, 969 (9th Cir. 2009); *see also Starr*, 652 F.3d at 1216.

[14] 21 U.S.C. § 360c *et seq*.

[15] *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008).

[16] 21 U.S.C. § 360k(a).

Because the MDA preempts only requirements that are "different from, or in addition to" the federal requirements,[17] it does not bar "a state-law claim for violating a state-law duty that parallels a federal-law duty under the MDA."[18]

2. Implied preemption

The Supreme Court in *Buckman Co. v. Plaintiffs' Legal Comm.*, held that, in addition to express preemption, the MDA also impliedly preempts "state-law fraud-on-the-FDA" claims—claims that the manufacturer made fraudulent representations to the FDA in the course of obtaining pre-market approval of a device.[19] If plaintiffs were allowed to maintain fraud-on-the-agency claims, the Court reasoned, such claims would conflict with, and would therefore be impliedly preempted by, the FDA's statutory responsibility to "police fraud consistently with the Administration's judgment and objectives."[20] The Court ruled that such claims are federal in nature because they do not rely on "traditional state tort law which had predated the federal enactments in question[]."[21]

B. Whether Spellman's Complaint Satisfies Rule 8(a)

S&N argues that the complaint is insufficient under Rule 8(a) because it lacks well-pleaded facts that show that S&N violated the FDA's regulations. S&N contends that the complaint "merely recites a laundry list of federal regulations S&N supposedly violated" without connecting any of the violations to specific facts.[22] Without well-pleaded regulatory violations, S&N argues, the complaint cannot overcome S&N's

---

[17] *Id.*

[18] *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1228 (9th Cir. 2013) (en banc).

[19] 531 U.S. 341, 348 (2001).

[20] *Id.* at 350.

[21] *Id.* at 353.

[22] Doc. 16 at 2.

express preemption defense.[23] In response, Spellman does not point to any specific facts that support her allegations that S&N violated the FDA's regulations. As she does in her complaint, she merely concludes without explanation that S&N violated the regulations.[24]

As an initial matter, it should be noted that federal preemption is an affirmative defense upon which the defendant bears the burden of proof.[25] Rule 8(a), which states that the complaint must include "a short and plain statement of the claim showing that the pleader is entitled to relief," does not apply to affirmative defenses. Affirmative defenses are addressed in Rule 8(c), which states that affirmative defenses may be pleaded in response to a complaint.[26] Because a complaint "need not anticipate or attempt to circumvent affirmative defenses,"[27] Rule 8(a) does not inherently require Spellman to plead any regulatory violations in order to sufficiently state her two Arizona-law claims.[28]

This does not end the discussion, however, because S&N's alleged regulatory violations play a critical role in Spellman's state-law claims. In order to establish a prima facie case of strict liability under Arizona law, Spellman must show that the BHR system is (1) "defective and unreasonably dangerous;" (2) "the defective condition existed at the time it left [S&N's] control;" and (3) "the defective condition is the

---

[23] *Id.* at 1.

[24] Doc. 21 at 3.

[25] *See Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 251 n.2 (2011); *Dilts v. Penske Logistics*, LLC, 769 F.3d 637, 649 (9th Cir. 2014); *Hunter v. Philip Morris USA*, 582 F.3d 1039, 1044 (9th Cir. 2009); *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1342 n.2 (10th Cir. 2015); *Bausch v. Stryker Corp.*, 630 F.3d 546, 561 (7th Cir. 2010).

[26] Fed. R. Civ. P. 8.

[27] *Bausch*, 630 F.3d at 561. *See also Jones v. Bock*, 549 U.S. 199, 216 (2007).

[28] *See Bausch*, 630 F.3d at 561–62; *Caplinger*, 784 F.3d at 1342 n.2. See *also cf. Albino v. Baca*, 747 F.3d 1162, 1169 (9th Cir. 2014) (en banc).

proximate cause of [her] injuries and property loss."[29] To establish negligence, Spellman must show "(1) a duty owed to [her], (2) a breach thereof and (3) an injury proximately caused by the breach."[30] For each of these torts, Spellman has incorporated S&N's regulatory violations into the statement of her claims: her strict liability cause of action alleges that the BHR system was unreasonably dangerous due to S&N's regulatory violations,[31] and her negligence cause of action alleges that S&N breached a duty to her by violating the FDA's regulations.[32] Thus, S&N's alleged regulatory violations are essential to Spellman's statement of her two claims. Although no heightened pleading standards apply, Rule 8(a) requires Spellman to plead sufficient factual matter to render plausible the alleged regulatory violations.

When analyzing whether a complaint's allegations satisfy Rule 8(a), courts employ a two-step process.[33] Courts "begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth."[34] If the court identifies well-pleaded factual allegations, it proceeds to the next step, under which it assumes the veracity of the allegations and determines "whether they plausibly give rise to an entitlement to relief."[35] Spellman's complaint fails at the first step. The complaint merely concludes, without any factual context, that S&N violated the various listed regulations. On the face of Spellman's complaint it is possible that S&N violated the

---

[29] *Dietz v. Waller*, 685 P.2d 744, 747 (Ariz. 1984).

[30] *Boyle v. City of Phoenix*, 563 P.2d 905, 906 (Ariz. 1977).

[31] Doc. 1 at 4 ¶ 13.

[32] *Id.* at 8 ¶ 22.

[33] *Eclectic Properties E., LLC v. Marcus & Millichap Co.*, 751 F.3d 990, 995–96 (9th Cir. 2014).

[34] *Iqbal*, 556 U.S. at 679.

[35] *Id.*

FDA's regulations, but the complaint does not include any "factual enhancement" to cross "the line between possibility and plausibility."[36] Dismissal is appropriate.

Spellman's opposition relies primarily on *Stengel* and *Bausch*, but to no avail. *Stengel* is inapposite because there the Ninth Circuit's decision rested on the merits of whether the state-law claims were preempted, not whether the complaint satisfied the *Twombly* standard.[37] With regard to *Bausch*, Spellman correctly notes that the Seventh Circuit held that Rule 8(a) does not require the complaint to identify specific federal regulations that were allegedly violated.[38] Even so, *Bausch* does not stand for the proposition that the complaint need not plausibly allege regulatory violations at all. The *Bausch* plaintiff alleged that the FDA had informed the defendant that its manufacturing methods did not conform to "industry and regulatory standards."[39] According to the Seventh Circuit, this allegation satisfied Rule 8(a) because it plausibly alleged "regulatory violations."[40] Spellman's complaint lacks analogous factual enhancement.

V. CONCLUSION

Based on the preceding discussion, Defendant's motion to dismiss at docket 16 is GRANTED without prejudice to Plaintiff's ability to attempt to file an amended complaint that complies with the standards set out in *Twombly*. Plaintiff may file a

---

[36] *Twombly*, 550 U.S. at 557.

[37] *See Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013), rev'd on other grounds by *Stengel*, 704 F.3d at 1228 (The district court "did not dismiss the Stengels' complaint on the ground that it did not conform to the *Twombly* standard, but instead on the ground that the Stengels' claims were preempted.").

[38] 630 F.3d at 560.

[39] *Id.* at 559.

[40] *Id.*

motion to amend her complaint within 21 days. If she does not do so, this case will be dismissed without further notice.

DATED this 24th day of September 2016.

/s/ JOHN W. SEDWICK
SENIOR JUDGE, UNITED STATES DISTRICT COURT